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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,825	01/11/2002	Yasunori Takada	56769 (71526)	2372

21874 7590 06/13/2007  
EDWARDS ANGELL PALMER & DODGE LLP  
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BOSTON, MA 02205

EXAMINER
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WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,825	<b>Applicant(s)</b> TAKADA ET AL.	
	<b>Examiner</b> Edward J. Webman	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al.

Patel et al teach a topical gel composition containing medicaments (abstract). 0.005% to about 10% medicament is specified (column 4 lines 48-49). Diclofenac is disclosed (column 4 line 67). Ammonium chloride at 0.01-5% is specified (column 8 lines 19-38). Sustained efficacy is disclosed (column 3 line 13).

It would have been obvious to one of ordinary skill in the art to make a composition comprising a gel including diclofenac and ammonium chloride to achieve the beneficial effect of sustained efficacy in view of Patel et al. As to the claimed molar ratio, the molar range of diclofenac is 0.0002-0.9 moles per liter and that of ammonium chloride is 0.002-0.3 moles /per liter. That is, the molar ranges overlap, including 1:1 ratio. An optimum suitable range is obtained by routine experimentation.

Claims 1, 4, 5, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledger et al in view and Inagi et al.

Ledger et al teaches a matrix for transdermal administration of a drug and an antigen processing-inhibiting agent is disclosed (abstract). 0.2%-20% weak base antigen processing-inhibiting agent of the drug is disclosed (column 9 lines 64-68).

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Ammonium chloride is specified (column 5 line 34). Analgesic agents including ibuprofen are disclosed (column 4 lines 45 and 63). An adhesive layer containing the agent and drug is specified (column 7 lines 8-9). Ointments are disclosed (column 6 line 37). Reducing sensitization is specified (column 3 lines 34-37).

It would have been obvious one of ordinary skill to make a matrix comprising an analgesic such as ibuprofen and ammonium chloride to achieve the beneficial effect of reducing sensitization. As to the claimed diclofenac and adhesive base, Inagi et al teach the equivalence of ibuprofen to diclofenac as an analgesic (column 8 lines 1-8) in an acrylic adhesive base material (abstract). Thus, it would have been further obvious to use diclofenac as the analgesic and acrylic as an adhesive in the composition of Ledger et al in view of the fact that the former is known in the art as equivalent to ibuprofen and the latter is known in the art as an adhesive in view of Inagi et al. As to the claimed molar ratio, 0.2-20% ammonium chloride of diclofenac is equivalent to 0.04-0.4 moles of the ammonium chloride to 0.3 moles of diclofenac. That is, the molar range of ammonium chloride overlaps the molar amount of diclofenac to include a 1:1 ratio. An optimum suitable range is obtained by routine experimentation.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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